UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	Honorable Joel Schneider, Magistrate Judge

WHOLESALER DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS

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INTRODUCTION

Plaintiffs have managed to turn what should be a basic product-recall, manufacturing defect claim into three complaints-worth-of legal conclusions that assert every conceivable theory against every conceivable defendant, with no specificity as to anyone. It is hard to imagine a tort or contractual theory or equitable remedy Plaintiffs fail to invoke on behalf of some purported class. Yet, Plaintiffs do not support their wide-ranging theories with factual allegations, particularly with regard to Wholesale pharmaceutical distributors ("Wholesalers") – pass-through entities protected under most states' laws as long as they do not alter the product they sell or have direct contact with consumers. The result is a tangled web of allegations and bare legal conclusions the Plaintiffs leave to the Court to sort out.

As to Wholesalers, the task is straightforward. Many of Plaintiffs' claims are expressly preempted or fall within FDA's primary jurisdiction. Plaintiffs' assertions of fraud, deceptive practices, consumer protection and unfair trade violations, and unjust enrichment, are unsupported by any factual allegation of wrongdoing that, if proven, could establish such claims against Wholesalers. Plaintiffs' personal injury and medical monitoring suits fail under Innocent Seller statutes and because Wholesalers do not manufacture the product. Finally, Plaintiffs' contractual warranty claims fail because, as Plaintiffs' pleadings

demonstrate, Wholesalers made no warranties to Plaintiffs. In sum, Plaintiffs' creative attempts to include all levels of the pharmaceutical supply chain through novel legal assertions, unencumbered by actionable facts, fail to state claims as a matter of law against Wholesalers, and, as a result, should be dismissed.

FACTUAL BACKGROUND REGARDING WHOLESALERS

Wholesalers play an integral but limited role as a pass-through in the pharmaceutical supply chain; Wholesalers distribute product between pharmaceutical Manufacturers and Pharmacy Defendants ("Pharmacies"), without exercising any control over the manufacture or labeling of the products.[1] Wholesalers do not in the normal course have any relationship or contact with Pharmacies' customers or consumers of the products.[2] Wholesalers' uniquely insulated role in the supply chain means that many of Plaintiffs' claims are inapplicable to them and necessitates the dismissal of these claims.

In particular, by virtue of Wholesalers' position in the supply chain, there is no privity between Plaintiffs and Wholesalers; Plaintiffs admit that Wholesalers do not sell directly to them. *See, e.g.,* PIMC. ¶¶ 127-128; MMMC ¶¶ 139-140. Nor do Wholesalers make any representations directly to Plaintiffs. As such, any claims

[1] Repackagers are similarly situated with the exception of adding new packaging to the products.

[2] https://www.hda.org/~/media/pdfs/communications/primary-pharmaceutical-distributors.ashx?la=en

requiring privity between the parties must be dismissed, as discussed *infra* and outlined in Wholesalers' Compendium of Charts at Charts 6, 7, and 8.

ADOPTION OF ARGUMENTS

Manufacturers' Memorandum of Law in Support of their Motion to Dismiss ("Mfrs.' Mem."), and Pharmacies' Memorandum of Law in Support of their Motion to Dismiss ("Pharmacies' Mem."), both present a number of grounds for dismissal of all Complaints as against all Defendants, including Wholesalers.[3] Therefore, in order to avoid repeating duplicative arguments for the Court's consideration, Wholesalers adopt and incorporate herein all arguments in those Memoranda that provide grounds for dismissal of Wholesalers from Plaintiffs' Complaints, specifically including Mfrs.' Mem. Sections I, II, III, IV, and V of the Argument and Pharmacies' Mem. Section III. [4]

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[3] Wholesalers also reiterate Manufacturers' position that a number of Defendants not only seek dismissal for lack of subject matter jurisdiction under Rule 12(b)(1), but would also move this Court to dismiss for lack of personal jurisdiction under Rule 12(b)(2) but for the Court's decision to exclude personal jurisdiction from its order allowing Rule 12(b) motions. Though Defendants wish to respect the Court's decision, they must preserve their rights and defenses against waiver under Rule 12(h)(1)(A). Therefore, Wholesalers join Manufacturers' request to grant leave to file a supplemental 30-page memorandum addressing personal jurisdiction.

[4] Distributors and re-packagers are similarly situated to Wholesalers inasmuch as they have no involvement in the manufacturing process; nor do they advertise or make statements about generic drugs to consumers. Subject to their slightly different roles with respect to packaging/labeling, all distributors and re-packagers in the MDL join in Wholesalers' arguments for dismissal, and in particular, adopt the following brief sections by reference: I (B) and II-III.

ARGUMENT

Wholesalers' unique role means that they are shielded from products liability as Innocent Sellers who serve as a mere conduit for products passing between Manufacturers and Pharmacies. In addition, Wholesalers' role in the supply chain also means that Plaintiffs cannot meet the Article III standing threshold for claims against those Defendants. Many of Plaintiffs' claims are expressly preempted by the Drug Supply Chain Security Act ("DSCSA") or fall within FDA's primary jurisdiction. Finally, Plaintiffs' 'shotgun' pleadings are facially deficient and lacking facts sufficient to support the various elements of Plaintiffs' remaining claims against Wholesalers. For these and other reasons, the Court should dismiss Plaintiffs' Complaints against Wholesalers in their entirety.

I. WHOLESALERS' UNIQUE ROLE IN THE SUPPLY CHAIN AFFECTS PLAINTIFFS' CLAIMS AGAINST THESE DEFENDANTS.

Wholesalers do not design, manufacture, label, or test valsartan-containing drugs ("VCDs"). Instead, Wholesalers' role is limited to distribution, a fundamental fact which Plaintiffs do not dispute. *See, e.g.,* PIMC. ¶¶ 127-128; MMMC ¶¶ 89, 139-140; ELMC ¶ 113, 186-187. Wholesalers purchase VCDs in bulk directly from Manufacturers and then sell VCDs directly – unopened, in their original Manufacturer bottles with labels created by Manufacturers and approved by FDA – to Pharmacies, who then sell the VCDs to consumers. Pharmacies are

reimbursed through complex TPP and Pharmacy Benefit Manager schemes that do not affect Wholesalers' compensation. Thus, Wholesalers are protected as Innocent Sellers in a majority of states, and entitled to dismissal of product liability claims against them. *See* Chart 1.

A. Wholesalers are Innocent Sellers Protected From Products Liability Claims.

As discussed in detail in Section III of Pharmacies' Mem., which is adopted herein, many states have recognized the fundamental unfairness of holding Innocent Sellers who served as a mere conduit passing an unchanged product from a seller to a buyer, such as Wholesalers here, liable for product liability when they could not and did not exercise any control over the design, formulation, manufacture, or labeling of VCDs. These laws "immunize innocent sellers who are not actively negligent, but instead are mere conduits of a product." *Nazari v. Kohler Co.*, No. 07-50188, 2008 U.S. App. LEXIS 21531, at *9 (5th Cir. Oct. 13, 2008) (explaining the purpose of Texas's Innocent Seller statute is "to avoid holding an innocent seller liable for a defective product manufactured by another"); *Ruiz v. Wintzell's Huntsville, L.L.C.*, No. 5:13-cv-02244-MHH, 2017 U.S. Dist. LEXIS 159547, at *22 (N.D. Ala. Sep. 28, 2017) ("The purpose of Alabama's innocent seller statute . . . is to protect distributors who are mere conduits of a product, presumably because they are not positioned to inspect for product defects already extant when the products come into the distributor's

possession."); Miss. Code Ann. § 11-1-63 (explaining, in Mississippi's Innocent Seller statute, that the intent of the statute is "to immunize innocent sellers who are not actively negligent, but instead are mere conduits of a product").

The majority of Innocent Seller statutes call for the dismissal of all product liability claims, no matter the specific cause of action or theory alleged. There are generally three requirements to establish entitlement to dismissal under an Innocent Seller statute. First, the product's manufacturer be identified.[5] Here, the applicable Manufacturers are already parties to this litigation, and each Plaintiff or Class Representative will be able to conclusively identify the Manufacturer of the VCD purchased and/or consumed through pharmacy records and NDC numbers. Second, an Innocent Seller must not have modified, altered, or exerted control over the design, manufacture, or labeling of the product. Plaintiffs' allegations make clear that the design, testing, manufacturing, packaging, and labeling of the product – and, indeed, the alleged contamination of VCDs – occurred before Wholesalers

[5] Two states, Missouri and New Jersey, require submission of an affidavit identifying the manufacturer. These rules are procedural, not substantive, and thus not a barrier to dismissal under Rule 12(b)(6) in federal court. *See Crosby v. Georgakopoulos*, 2005 U.S. Dist. LEXIS 32238, *23 (D.N.J. June 24, 2005) (granting the defendant's motion to dismiss where the defendant was clearly not the manufacturer of the product at issue); *Thomas v. Brown & Williamson Tobacco Corp*., 2006 U.S. Dist. LEXIS 28261 (W.D. Mo. Apr. 28, 2006) (finding that "this statute has been held to be substantive, rather than a procedural device, and therefore [the innocent seller statute] is applicable in federal court" and finding joinder of a seller to be fraudulent).

ever purchased the products, and there are no allegations that Wholesalers altered or modified the product. *See* PIMC ¶¶ 236-247. Thus, Wholesalers clearly fulfill the first and second elements to obtain Innocent Seller statute protection.

Finally, as set forth in Pharmacies' Mem. Section II.B.2, which is incorporated fully herein, the Innocent Seller must not have actual or constructive knowledge of the defect at issue. Here, Plaintiffs acknowledge the defect alleged was not obvious – it is a microscopic contaminant not visible to the naked eye, even in an opened container. Plaintiffs do not plausibly allege that Wholesalers had actual knowledge of VCDs' contamination before the recalls. To the contrary, Plaintiffs allege that Manufacturers intentionally concealed and destroyed evidence of contamination.[6] Plaintiffs provide no support for their allegations that Wholesalers somehow must have known about this allegedly concealed, destroyed information. Moreover, Plaintiffs do not allege facts that would have put Wholesalers on constructive notice of *actual* contamination in VCDs, as opposed to the possibility of problems at certain Chinese/Indian manufacturing facilities. Because Wholesalers are entitled to the protections of various Innocent Seller laws, they are entitled to dismissal of Plaintiffs' claims in the states outlined in Chart 1.

[6] Wholesalers disclaim any agreement or endorsement of Plaintiffs' allegations in this regard.

B. Plaintiffs Lack Standing to Sue the Entire Supply Chain and Do Not Allege Injury-in-Fact in Relation to Wholesalers.

In addition to incorporating the arguments in Section II of Mfrs.' Mem. on Article III standing, Wholesalers' unique position in the supply chain also means that Plaintiffs cannot meet the Article III standing threshold for claims against them. For any Plaintiff to have Article III standing to sue Wholesalers, that Plaintiff must allege facts showing a substantial likelihood that Wholesalers' conduct caused the plaintiff's harm. *Pub. Interest Research Grp. v. Powell Duffryn Terminals*, 913 F.2d 64, 72 (3d Cir. 1990). Unless that alleged harm "fairly can be traced to the challenged action" of Wholesalers, standing does not exist. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (quoting *Simon v. E. Ky. Welfare Rights Org.,* 426 U.S. 26, 41-42 (1976)); *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990); *Winer Family Trust v. Queen*, 503 F.3d 319, 325 (3d Cir. 2007).

Plaintiffs have not alleged *any* facts suggesting that Wholesalers' conduct caused Plaintiffs' alleged harm, or caused with substantial likelihood the alleged harm, whether stated as personal injury, the need for medical monitoring, or economic loss in the various Complaints. Plaintiffs do not allege that, *but for Wholesalers' conduct*, the alleged contamination would not have occurred, that Plaintiffs would not have purchased and/or consumed allegedly contaminated VCDs, or that Wholesalers' actions were a substantial factor in the alleged contamination or consumption. Nor are there facts regarding Wholesalers in any of

the Complaints that would support those allegations, if they existed. Furthermore, even a theory of causation related to Wholesalers' imagined control over Manufacturers' practices – allegations that hinge on Wholesalers possessing "a degree of influence over [others] that was not plausible on the limited allegations in the Complaint[s]" – does not establish standing because the required causal connection and traceability between the alleged harm and the conduct are not present. *Sherfey v. Johnson & Johnson*, No. 12-4162, 2014 U.S. Dist. LEXIS 57735, at *14-15 (E.D. Pa. Apr. 25, 2014) (dismissing defendants with prejudice because they did not have influence over J&J's recall decisions nor knowledge of the specific defects in the Infants' Tylenol) (citing *In re McNeil Consumer Healthcare, et al., Mktg. and Sales Litig.*, MDL No. 2190, 2011 U.S. Dist. LEXIS 76800, 2011 WL 2802854, at *1 (E.D. Pa. July 15, 2011); *Moore v. Johnson & Johnson*, 83 F. Supp. 3d 629 (E.D. Pa. 2014)).

Here, Wholesalers did not design, formulate, or manufacture VCDs and do not have influence or control over the manufacturing practices of the API or Finished Dose Manufacturing Defendants. Wholesalers are not capable of testing the billions of different pills that they transport each year, nor is there any state law duty or federal regulatory requirement to do so. *See Temporomandibular Joint Implant Recipients v. E.I. Du Pont De Nemours & Co. (In re Temporomandibular Joint Implants Prods. Liab. Litig.)*, 97 F.3d 1050, 1059 (8th Cir. 1996) ("[A]

distributor, acting as a mere conduit of a product, is only liable for known dangers. If a product has at most a latent defect, 'there is no duty on the distributor to inspect for possibly inherent defects.'") (quoting American Law of Products Liability 3d § 5.23, at 43-44 (Matthew J. Canavan, ed. pt. 3, 1994). Any testing requirements lie with Manufacturers and FDA, as does the development of the pharmaceutical labels. Wholesalers have no plausible degree of influence over the manufacture or the contents of the product or labeling sufficient to establish a causal connection. And Plaintiffs have not alleged any facts suggesting that, but for Wholesalers' conduct, the alleged contamination would not have occurred or that the Plaintiffs would not have purchased and/or consumed VCDs. Thus, Plaintiffs do not have standing to sue Wholesalers, and their claims must be dismissed.

II. PLAINTIFFS' CLAIMS AGAINST WHOLESALERS ARE PREEMPTED UNDER THE DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) AND/OR SUBJECT TO PRIMARY JURISDICTION.

Plaintiffs' claims that allege a failure of Wholesalers to adequately track or trace product through the supply chain are expressly preempted by the DSCSA and should be dismissed. Additionally, any claims that assert that Wholesalers' failure to test VCDs allowed contaminated product to be sold to consumers – such as Plaintiffs' causes of action for breach of implied warranty, strict liability failure to warn consumers, negligent misrepresentation, and certain negligence and

manufacturing defect claims – invade the province of the FDA and primary jurisdiction applies.

A. Plaintiffs' Claims Against Wholesalers Are Preempted Under the DSCSA.

In 2013, Congress passed the DSCSA in an effort to secure the supply chain for prescription pharmaceutical drugs. The DSCSA is intentionally broad and comprehensive, governing all participants in the supply chain for prescription pharmaceutical drugs, from manufacturers to retail pharmacies. 21 U.S.C. § 360eee to 360eee-5. To combat the patchwork of inconsistent state requirements prior to the enactment of the DSCSA, Congress mandated that the DSCSA be a uniform national standard. To effectuate this uniform national standard, Congress included an express preemption provision that specifically precludes imposition of any state requirements that are "inconsistent with, more stringent than, or in addition to" the DSCSA:

> Beginning on November 27, 2013, no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) which are inconsistent with, more stringent

> than, or in addition to, any requirements applicable under . . . this part (or regulations issued thereunder) . . .[7].

21 U.S.C. 360eee-4(a). This preemption covers any claim that Wholesalers were negligent for failing to track VCDs by lot number as product tracking is not required by the DSCSA.

B. Plaintiffs' Claims Fall Within FDA's Primary Jurisdiction.

As discussed in detail in Section III of Mfrs.' Mem., which is adopted herein in its entirety, the FDA oversees compliance with and enforcement of the FDCA, and is vested with broad and exclusive authority to promulgate regulations, provide guidance, and undertake enforcement actions. *See* 21 U.S.C. §§ 321, 337(a), 371-72, 375, 393(a). Primary jurisdiction applies "whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body." *Fulton Cogeneration Assocs. v. Niagara Mohawk Power Corp.*, 84 F.3d 91, 97 (2d Cir. 1996) (citing *United States v. Western Pac. R.R. Co.,* 352 U.S. 59, 64, 77 S.Ct. 161, 165, 1 L.Ed.2d 126 (1956)). When an activity is arguably subject to an administrative agency's expertise, such as the FDA, federal courts must defer to

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[7] The two ellipses reference requirements for wholesaler and third-party logistics providers, as does subsection (b) of 21 U.S.C. 360eee-4. "This part" refers to all of the Drug Supply Chain Security Act, 21 360eee through eee-4. The Public Law version of the Act uses the term "this subchapter," which references Subchapter H, which includes definitions (360eee) and specific requirements (360eee-1). P.L. 113-54.

the exclusive competence of that agency. *In re Human Tissue Prod. Liab. Litig.*, 488 F. Supp. 2d 430, 432 (D.N.J. 2007). The FDA has broad statutory power to regulate drug sourcing, manufacturing, packaging, labeling, testing, tracing and sales and has done so *exhaustively*. *See* Code of Federal Regulations Title 21, Chapters 1-1499. The FDA's Center for Drug Evaluation and Research (CDER) is tasked with ensuring that safe and effective drugs are available to improve the health of the people in the United States.[8] FDA is in the best position to evaluate Plaintiffs' allegations regarding testing, as those assertions squarely invoke FDA's prescribed testing procedures and requirements.

Plaintiffs' causes of action for breach of implied warranty, strict liability failure to warn consumers, negligent misrepresentation, and certain negligence and manufacturing defect claims that rely on the allegation that Wholesalers failed to test should thus be dismissed because they invade the province of the FDA and primary jurisdiction applies. *See, e.g.*, *Heller v. Coca-Cola Co.*, 230 A.D.2d 768, 769, 646 N.Y.S.2d 524, 525 (1996) (finding that primary jurisdiction applied to the plaintiffs' tort claims regarding alleged mislabeling, which was in the province of the FDA). Because the enforcement of the FDCA and the regulatory framework regarding product testing are within the exclusive authority of the FDA, all of

[8] FDA, Drugs (6/03/2020), https://www.fda.gov/drugs.

Plaintiffs' claims must fail as all are premised on the alleged failure by Wholesalers to conduct testing.

III. PLAINTIFFS' REMAINING CLAIMS ARE NOT ADEQUATELY PLED OR LEGALLY VIABLE AND SHOULD BE DISMISSED.

For the reasons stated in Section V of Mfrs.' Mem. and incorporated herein, Plaintiffs' remaining claims should be dismissed due to their failure to state a claim on their face and pleading defects. Moreover, additional issues exist that support the dismissal of these claims against Wholesalers in particular.

A. Plaintiffs Do Not Plead a Legally Viable Unjust Enrichment Claim Against Wholesalers.

With respect to Plaintiffs' unjust enrichment claims, Wholesalers adopt the reasons set forth in Mfrs.' Mem. Section V.F. and Pharmacies' Mem. Section II.B.4., all of which are incorporated herein. Plaintiffs' unjust enrichment claims further fail against Wholesalers in particular because Plaintiffs do not allege improper enrichment by Wholesalers at the expense of Plaintiffs. Wholesalers are alleged to have sold VCDs to Pharmacies and there is no allegation that Wholesalers had knowledge of alleged contamination of those VCDs pre-recall or that they sold any recalled VCDs. It is fundamental, then, that any sort of claim that payment to Wholesalers by Pharmacies was somehow unjust – or more particularly, unjust as to Plaintiffs who should receive Wholesalers' profits as a result– fails due to the dearth of allegations sufficient to invoke the claim. *See*

Chart 2. Unjust enrichment is an equitable theory that rests on the occurrence of some wrongdoing that makes the defendant's retention of remuneration unfair. *Albinger v. Harris*, 48 P.3d 711, 716 (Mont. 2002) ("The doctrine of unjust enrichment is an equitable means of preventing one party from benefitting by his or her wrongful acts, and, as such requires a showing of misconduct or fault to recover."); *In re: Cheerios Mktg. & Sales Practices Litig.*, Civil Action No. 09-cv-2413, 2012 U.S. Dist. LEXIS 128325, at *35-38 (D.N.J. Sep. 10, 2012). Plaintiffs do not allege any such wrongdoing or unfairness by Wholesalers.

Wholesalers, of course, were not in privity with Plaintiffs and the unjust enrichment claim cannot survive the fact that Plaintiffs fail to allege any direct benefit provided to Wholesalers. *In re Rezulin Prods. Liab. Litig.*, 392 F. Supp. 2d 597, 619–21 (S.D.N.Y. 2005) (dismissing unjust enrichment claim due to lack of privity, a necessary element of an unjust enrichment claim under New Jersey law); *see* Chart 3.

Even putting aside Wholesalers' position vis-à-vis Plaintiffs, in many jurisdictions, to establish unjust enrichment, there must be a failure of remuneration. *Adamson v. Ortho-McNeil Pharm., Inc.*, 463 F. Supp. 2d 496, 505 (D.N.J. 2006). "Unjust enrichment is not a viable theory… in circumstances in which a consumer purchases specific goods and receives those same specific goods." *In re: Cheerios Mktg. & Sales Practices Litig.*, at *36-37 (D.N.J. Sep. 10,

2012), *citing, Adamson v. Ortho-McNeil Pharm., Inc.*, 463 F. Supp. 2d 496, 505 (D.N.J. 2006); *see also, Hoffman v. Cogent Sols. Grp., LLC*, 2013 U.S. Dist. LEXIS 176056, at *13 (D.N.J. 2013). Here, Plaintiffs' Complaints demonstrate they specifically purchased and received VCDs. Unjust enrichment is unavailable.

Finally, many states prohibit unjust enrichment claims where there is an adequate remedy at law. *See* Charts 4, 5. Plaintiffs do not allege that they lack an adequate remedy at law.[9] To the contrary, Plaintiffs' Economic Loss Master Complaint (ELMC) alleges an array of remedies at law, and it is undisputed the CVDs were sales of goods. For all of the foregoing reasons, Plaintiffs' unjust enrichment claims against Wholesalers should be dismissed in their entirety.

B. Plaintiffs Do Not Plead Facts Supporting Their Unjust Enrichment Damages Claims Against Wholesalers.

The ELMC claims Plaintiffs paid for defective VCDs. It does not aver a factual basis for anything more than reimbursement of the specific cost of the drugs paid by customers. The law is clear that such claims for consequential damages and disgorgement should be stricken as unfounded.[10]

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[9] In addition to many states' prohibitions of unjust enrichment claims where there is an adequate remedy at law, many states mandate dismissal of an unjust enrichment claim if the plaintiff fails to *plead* the absence of an adequate remedy at law, as here. *See* Chart 4.

[10] Wholesalers do not concede that Plaintiffs are even entitled to reimbursement and reserve the right to address this later in this ligation should the unjust enrichment claim survive this motion practice.

Under the Restatement (Third) of Restitution and Unjust Enrichment (2011), an "Innocent Recipient" (§50) or a "Faultless Recipient" (§51)(1) cannot be liable as a matter of law for damage elements such as consequential damages, costs, or disgorgement. An "innocent recipient" is one who receives enrichment by mistake or who intentionally entered into the transaction at issue, but acted without any fault when the transaction went awry. §50 at Comment C. A "faultless but wrongful recipient," does not act with fault, but an otherwise legally actionable right may have been interfered with. §51 at Comment A. Pursuant to this, the only damages permitted against Wholesalers are, respectively, "reasonable value" of the benefit conferred (§51 Comment D[11]) or 1) "market value" of the benefit conferred, 2) interest, and 3) "proceeds as necessary to avoid unjust enrichment but…[not]…consequential gains." §51(2) and 53(1-3). Thus an innocent recipient is responsible for neither proceeds nor consequential gains.

Plaintiffs fail to aver facts that Wholesalers are anything more than "faultless recipients" or "innocent recipients" and are, as a matter of law, not liable for consequential damages, costs, interest or disgorgement.

C. There is No State Law Duty That Wholesalers Test VCDs.

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[11] The innocent recipient provisions differentiate between defendants who received the benefit by mistake versus those who intentionally intended to enter into the transaction. The law cited herein is the standard for those innocent recipients who intended to enter into the transaction.

Plaintiffs attempt to base a number of causes of action, in whole or in part, on an allegedly negligent "failure to test." It is axiomatic that without a duty there can be no negligence. Courts have consistently held there is no duty to test a product independent of the design, manufacture, or labeling of the product. *See, e.g., Drager v. PLIVA USA, Inc.,* 741 F.3d 470, 477 (4th Cir. 2014); *Kociemba v. G.D. Searle & Co.,* 707 F. Supp. 1517, 1527-28 (D. Minn. 1989); *Wolfe v. McNeil-PPC, Inc.,* 773 F. Supp.2d 561, 570 (E.D. Pa. 2011). It is undisputed Wholesalers did not design, manufacture, or prepare the warnings for the VCDs. Accordingly, Wholesalers could not have had a duty to test the VCDs and no cause of action against the Wholesalers, regardless how it is captioned, can be based on any alleged failure to test. At a minimum, that includes Plaintiffs' causes of action for breach of implied warranty, strict liability failure to warn, negligent misrepresentation, and certain negligence and manufacturing defect claims, all of which are premised on the theory that Wholesalers' alleged failure to test VCDs allowed contaminated product to be sold to consumers.

D. Plaintiffs' Breach of Express and Implied Warranty Claims Fail.

For the reasons set forth in Section V of Mfrs.' Mem. and incorporated herein, all of Plaintiffs' claims for breach of express and implied warranties fail to state a claim as to Wholesalers and should be dismissed. Plaintiffs do not identify a warranty or representation because: (1) they do not allege privity as required by

certain states; (2) they do not allege the existence of an affirmation of fact or promise made by *Wholesalers* as required under UCC § 2-313 and 2-314; and (3) they do not allege reliance as required by certain states. For these reasons the Court should dismiss all express and implied warranty claims against Wholesalers.

1. Plaintiffs Do Not and Cannot Allege Privity with Wholesalers.

Plaintiffs' breach of implied and express warranty claims should be dismissed for lack of privity. Privity is required for express or implied warranties under the laws of numerous states. *See* Charts 6. 7. Plaintiffs have not alleged and cannot allege privity with Wholesalers as required by certain states in order to state a claim for express or implied warranty. The Court should dismiss Plaintiffs' breach of warranty claims where privity is a required element.

2. Plaintiffs Do Not and Cannot Allege Any Express Affirmation or Promise Made by Wholesalers.

Plaintiffs do not plead that *Wholesalers* made any promise, affirmation, or representation regarding the VCDs at issue in this litigation. Of course they do not – Wholesalers have no contact whatsoever with Plaintiffs (or any consumers). Wholesalers do not manufacture or sell the product to Plaintiffs nor do they make any warranties whatsoever to Plaintiffs. *See, e.g.,* PIMC ¶ 128. Plaintiffs allege only boiler-plate conclusions about warranties directed to "Defendants" collectively and do not single out any specific representation by any Wholesaler.

See, e.g., ELMC ¶ 8, 11-34. These vague and undifferentiated allegations are insufficient to demonstrate that any Wholesaler made an affirmation, promise, or description about the product to Plaintiffs. *See Arlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691, 707 (D.N.J. 2011) (dismissing express warranty claim because the plaintiff failed to "identify specific affirmations or promises by Defendants").

3. Plaintiffs Do Not Allege that an Express Warranty Formed the Basis for Any Bargain.

Section 2-313 of the UCC requires reliance by a plaintiff, i.e. that a seller's statement is "part of the basis of the bargain." S*ee, e.g., Coffey v. Dowley Mfg., Inc.,* 187 F. Supp. 2d 958, 969 (M.D. Tenn.2002), *aff'd,* 89 F. App'x 927 (6th Cir. 2003) (finding that to establish a prima facie claim for breach of express warranty a plaintiff must prove "that the buyer was in fact induced by the seller's acts"); *Global Truck & Equip. Co. v. Palmer Mach. Works, Inc.*, 628 F.Supp. 641, 651–52 (N.D. Miss. 1986) (finding that buyer could not recover for breach of express warranty absent proof that buyer relied on statements prior to or contemporaneously with sale); *see also* Chart 8. As set forth in Section V of Mfrs.' Mem., Plaintiffs allege no express warranties, so it follows that none can fairly be alleged against Wholesalers. No express warranty by any Wholesaler formed the basis of any bargain, and Plaintiffs' express warranty claims should be dismissed.

4. Plaintiffs Do Not Allege the Injury Required to Support a Claim of Breach of Implied Warranty.

To sustain a claim of breach of implied warranty Plaintiffs must plead impaired functionality of the VCDs caused an actual injury to Plaintiffs. *See, e.g.*, *Hoffman v. Nutraceutical Corp.*, No. CIV.A. 12-5803 ES, 2013 WL 2650611, at *4 (D.N.J. June 10, 2013) (breach of implied warranty claim requires that the alleged "defect proximately caused injury to the ultimate consumer") (internal citations omitted); *Bowman v. RAM Med., Inc.*, No. I O-CV-4403 DMC MF, 2012 WL 1964452, at *5 (D.N.J. May 31, 2012) ("Plaintiffs fail to assert any injury, and in fact disclaim any physical harm, resulting from the product. . . . Plaintiffs can sustain neither a claim of breach of implied warranty of merchantability nor fitness for a particular purpose"); *Crozier v. Johnson & Johnson Consumer Companies, Inc.*, 901 F. Supp. 2d 494, 509 (D.N.J. 2012) (dismissing implied warranty claims that "contain no allegations whatsoever about any injuries that Plaintiffs sustained," noting that "establishing a breach of the implied warranties of merchantability . . . requires a showing regarding the product's functionality.")

As set forth in Section V of Mfrs.' Mem., Plaintiffs do not allege the VCDs did not work to lower their blood pressure, or make any allegations of impaired functionality of VCDs causing actual injury (physical or otherwise) resulting from the ingestion of the VCDs. Plaintiffs' claims for breach of implied warranty should therefore be dismissed.

E. Plaintiffs' Fraud Claims Against Wholesalers Do Not Meet the Heightened Pleading Standard for Fraud Claims.

Wholesalers assert and incorporate the arguments against Plaintiffs' fraud claims in Section V of Mfrs.' Mem. Additionally, Plaintiffs fail to allege that Wholesalers had any knowledge of the purported product defects, and fail to plead any factual allegations demonstrating reliance by Plaintiffs on any alleged intentional misrepresentation or omission made by Wholesalers. Finally, Plaintiffs do not allege facts demonstrating any special relationship between Wholesalers and Plaintiffs giving rise to a duty to disclose.

1. Plaintiffs Do Not Plead the Specifics of Any Alleged Fraudulent Statement or Misrepresentation on Which They Purportedly Relied.

As discussed in Section V of Mfrs'. Mem., Plaintiffs do not allege, specifically or otherwise, the 'who, what, where, or when' of any purportedly fraudulent representation by Wholesalers. Instead the Complaints allege generally that "each Defendant" collectively made fraudulent or misleading representations, but mention no specific facts regarding intentional misrepresentations or omissions made by Wholesalers in particular. ELMC ¶ 365, 493; *see also, e.g.*, MMMC ¶ 322.

In fact, Plaintiffs do not inject any precision into the Complaints that would make Wholesalers aware of the "precise misconduct with which [they are] charged." *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007).

Consequently, Plaintiffs' allegations come nowhere near the level of specificity required to plead fraud against Wholesalers and should be dismissed.

2. Plaintiffs Do Not Allege that Wholesalers Knew of the Alleged Defects.

Plaintiffs' Complaints similarly include no factual allegations in support of their assertions that Wholesalers "knew, or reasonably should have known, that their misrepresentations were material false or misleading, or that the omission of material facts rendered such representations false or misleading." ELMC ¶ 496. For that reason, as well as those set forth in Section V of Mfrs.' Mem, the Court should dismiss Plaintiffs' fraud claims against Wholesalers for failing to adequately plead knowledge on the part of Wholesalers.

3. Plaintiffs Do Not Plead Reliance by the Class.

As an essential element of fraudulent misrepresentation, a plaintiff must allege reliance on the specific false statement or misrepresentation. *See Frederico*, 507 F.3d at 200 ("To state a claim for fraud under New Jersey law, a plaintiff must allege . . . a material misrepresentation of fact; . . . [and] reasonable reliance thereon by the other person). The element of reliance, like all other elements of fraud, must be pled with particularity. *See, e.g., Latraverse v. Kia Motors of Am., Inc.*, No. 10-6133 (RBK/AMD), 2011 WL 3273150, at *4 (D.N.J. July 27, 2011) (dismissing the plaintiff's common law fraud claim, in part, because "[t]he Complaint d[id] not allege . . . reasonable reliance with particularity."); *Witriol v.*

Conexant Syst., 2006 WL 3511155, at *7 (D.N.J. Dec. 4, 2006) (dismissing fraud claim where the plaintiff "fail[ed] to plead facts probative of actual reliance on specific statements" and therefore, "the allegations of reliance [we]re cursory and general, lacking the specificity that the Third Circuit requires to state a claim"; *see also Learning Works, Inc. v. Learning Annex, Inc.*, 830 F.2d 541, 546 (4th Cir. 1987) (noting that "reliance must be pleaded with particularity" and concluding that plaintiff's "fraud claim was subject to dismissal" for failure to allege the requisite reliance); *Scansource, Inc. v. Datavision-Prologix, Inc., et al.*, No. Civ.A. 04-CV-4271, 2005 WL 974933, at *2 (E.D. Pa. Apr. 26, 2005) (collecting cases and noting that "the clear weight of authority requires that the detrimental reliance of a fraud claim be pleaded with particularity under Rule 9(b).").

Here, however, Plaintiffs' claims fail to link the alleged reliance of Plaintiffs as a class to any particular fraudulent statement or misrepresentation by Wholesalers and do not properly plead the requisite reliance on any particular false statement or misrepresentation. *See, e.g.,* MMMC ¶ 483; ELMC ¶¶ 513-14.

4. Plaintiffs Have Not Alleged Any Duty to Disclose Owed by Wholesalers.

Plaintiffs' fraud claims based on concealment fail for the additional reason that they have not alleged that Wholesalers owed the requisite duty to disclose by virtue of a fiduciary or trust-based relationship between the parties. Critically, "'New Jersey courts will not imply a duty to disclose' in a case alleging fraudulent

concealment." *Arcand v. Brother Int'l Corp.*, 673 F. Supp. 2d 282, 305 (D.N.J. 2009) (quoting *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1185 (3d Cir. 1993). Such a duty arises only in: (1) fiduciary relationships, such as principal and agent, client and attorney, or beneficiary and trustee; (2) relationships where one party expressly reposits trust in another party; and (3) relationships involving intrinsically fiduciary transactions requiring a degree of trust to protect the parties. *Id*. (quoting *Lightning Lube*, 4 F.3d at 1185). Plaintiffs have not alleged any such special relationship. In fact, Plaintiffs' ELMC illustrates that no relationship *of any kind* exists between Plaintiff consumers and Wholesalers. *See, e.g.,* ELMC ¶ 151. Plaintiffs do not, and indeed, cannot, include facts alleging that a fiduciary relationship exists between Plaintiffs and Wholesalers. *Arcand*, 673 F. Supp. 2d at 305. The Court also should dismiss Plaintiffs' claims of fraudulent concealment and omission.

F. Plaintiffs Do Not Allege Facts to Support Negligent Misrepresentation/Omission Claims Against Wholesalers.

Plaintiffs' Complaints do not allege that Wholesalers negligently misrepresented (or omitted) any facts to Plaintiffs. Instead, Plaintiffs allege that *all Defendants* "made untrue representations of material facts and/or omitted material information to Plaintiffs, Plaintiffs' physicians, and the public at large," but do not identify any supporting facts specific to Wholesalers. *See* PIMC ¶ 513. Plaintiffs further allege that "Defendants were negligent" in making the unidentified

purported misrepresentations, but make no allegation specific to any Wholesaler. *Id*. ¶ 516. These vague allegations are insufficient to state a claim as to Wholesalers. *See, e.g., Greencort Condo. Ass'n v. Greencort Partners*, No. 04045 JAN.TERM 2004, 2004 WL 1088758, at *1 (Pa. Com. Pl. Apr. 30, 2004) (dismissing the plaintiff's negligent misrepresentation claim for failure to plead sufficient facts to state a claim including regarding any misrepresentation of material fact).

Plaintiffs' bare allegations also do not contain facts sufficient to support an ascertainable loss or injury sustained as a result of Wholesalers' alleged negligent misrepresentations. In cases involving breach of contract or misrepresentation, courts have required an estimate of out-of-pocket loss or loss in value to meet the ascertainable loss hurdle. *See Henderson v. Hertz Corp.,* No. A-3776-03, 2005 WL 4127090, at *7-8 (N.J. Super. Ct. App. Div. 2005) (citing *Thiedemann v. Mercedes-Benz USA, LLC*, 183 N.J. 234, 238, (2005)); *see also Hoffman v. Nutraceutical Corp.*, No. 12-5803 (ES), 2013 WL 2650611, at * (D.N.J. June 10, 2013) (noting that the "requirement to show a demonstration of loss in value . . . requires . . . that the customer was misled into buying a product that was ultimately worth less to the customer than the product he was promised.") (internal quotations omitted). Plaintiffs do not meet this burden.

While Plaintiffs allege that they suffered harm as a result of Defendants' misrepresentations (*see, e.g.,* PIMC ¶ 518; ELMC ¶ 524), Plaintiffs do not allege facts to support their boiler-plate allegations or to show that they suffered an economic loss or injury. *See, e.g.*, *Mason v. Coca-Cola Co.*, 774 F. Supp. 2d 699, 705 (D.N.J. 2011) (dismissing the plaintiffs' misrepresentation claims because they lacked facts showing how plaintiffs experienced any loss); *Solo v. Bed Bath & Beyond, Inc.,* Civ. 06–1908(SRC), 2007 WL 1237825, at *3 (D.N.J. Apr. 26, 2007) ("Plaintiff has failed to set forth either an out-of-pocket loss or a demonstration of loss in value sufficient to satisfy the ascertainable loss requirement.").

Finally, multiple states limit negligent misrepresentation claims to situations involving actual privity of contract between the parties, or a relationship close enough to approach privity, and Plaintiffs do not allege facts to support privity with Wholesalers. *See* Chart 9.

G. Plaintiffs Do Not Allege Any Facts Showing Negligence by Wholesalers.

Plaintiffs' negligence claims do not allege specific facts showing negligence on the part of any Wholesaler; instead, Plaintiffs lump Wholesalers in with all other Defendants in this action, noting that they are separate and distinct entities (PIMC ¶ ¶ 125 – 128), but failing to allege any negligence by *Wholesalers* that led to harm suffered by Plaintiffs. Plaintiffs generically assert that "[e]ach distributor

defendant is obligated under the DSCSA to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs." PIMC ¶ 388. Importantly, however, Plaintiffs fail to plead a breach of this duty by Wholesalers and do not plead any facts related to an alleged breach of this duty by Wholesalers that actually caused harm to Plaintiffs. It is not enough to merely allege that Wholesalers were in the supply chain without also alleging a specific breach of a specific duty causing injury; the negligence claims should be dismissed.

H. Plaintiffs Do Not Plead a Viable Cause of Action for State Consumer Fraud.

Plaintiffs assert claims against "each Defendant" for "unfair competition or unfair or deceptive acts or practice" in violation of consumer protection statutes in all 50 states. ELMC ¶¶ 543-554; PIMC ¶¶ 524-574. Plaintiffs then claim in conclusory fashion that "each Defendant knew, intended, or should have known, that their *fraudulent and deceptive* acts, omissions, or concealment would induce reliance and that reliance can be presumed under the circumstances[,]" (ELMC ¶ 548) and that Defendants' "course of *fraudulent conduct and fraudulent concealment* constituted acts . . . in violation of the consumer protection statutes . . . ." PIMC ¶ 575. (emphasis added)

Plaintiffs' claims for alleged violations of consumer protection statutes are subject to the same heightened pleading standard of Fed. R. Civ. P. 9(b) applicable to Plaintiffs' fraud claims, as discussed *supra* and in Section V of Mfrs' Mem. *See*

Mickens v. Ford Motor Co., 900 F. Supp. 2d 427, 435 (D.N.J. 2012). As with their fraud claims, Plaintiffs fail to provide the specificity required by Rule 9(b) to state an actionable claim for a violation of any consumer protection statute against Wholesalers. Plaintiffs' generic allegations that Defendants collectively engaged in unspecified "unfair or deceptive acts" or practices do not identify the 'who, what, where, or when' of these allegedly fraudulent, unfair, and/or deceptive acts and practices by Wholesalers. *See, e.g.*, ELMC ¶¶ 113-120, 411; PIMC ¶¶ 113-120. Without those necessary details, Plaintiffs' consumer fraud claims fail.

I. The PI Complaint Does Not Allege Any Facts That Would Justify Punitive Damages.

As set forth in Section V of Mfrs.' Mem., the PIMC does not state a plausible claim for punitive damages. Plaintiffs generically aver that Defendants collectively "knew, and/or had reason to know," that the VCDs ingested by Plaintiffs were unsafe or contained carcinogenic compounds. PIMC ¶¶ 414-15. Plaintiffs do not, however, allege any non-conclusory facts demonstrating that *Wholesalers* specifically knew of the alleged defects, which stem entirely from the manufacturing and design of VCDs.

Plaintiffs acknowledge Wholesalers' limited role in the supply chain and their lack of contact with Plaintiffs. *Id*. ¶¶ 126-28. Plaintiffs' PIMC contains no facts to support the allegation that Wholesalers were linked in any way to the manufacturing or design processes, or were privy to any knowledge about such

processes. Of course, without knowledge of the alleged manufacturing and design defects, Wholesalers could not have acted with the requisite gross negligence to support a claim for punitive damages even under the most lenient standard.

CONCLUSION

WHEREFORE, for the foregoing reasons, as well as those reasons applicable to Wholesalers as outlined in the co-Defendants' briefs, Wholesalers respectfully request the dismissal of all claims against them. *See* Chart 10.

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Respectfully submitted,

/s/ Jeffrey D. Geoppinger

Jeffrey D. Geoppinger, Esq.
Liaison Counsel for Wholesaler Defendants

Jeffrey D. Geoppinger, *Liaison Counsel for Wholesaler Defendants*
ULMER & BERNE LLP
600 Vine Street, Suite 2800
Cincinnati, OH 45202-2409
Tel.: (513) 698-5038
Fax: (513) 698-5039
Email: jgeoppinger@ulmer.com
Counsel for Amerisource Bergen

Andrew D. Kaplan
CROWELL & MORING
1000 Pennsylvania Avenue NW
Washington., D.C. 20004
Tel.: (202)624-1000
Fax: (202) 628-5116
Email: akaplan@crowell.com
Counsel for Cardinal Health Inc.

D'Lesli M. Davis

Ellie K. Norris
NORTON ROSE FULBRIGHT US LLP
2200 Ross Avenue, Suite 3600
Dallas, TX 75201-7932
Tel: (214) 855-8221
Fax: (214) 855-8200
Email:
dlesli.davis@nortonrosefulbright.com

Email: ellie.norris@nortonrosefulbright.com
Counsel for McKesson Corporation